IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

v.

RIDDHI USA, INC. and MOHD M. ALAM,

Defendants.

COMPLAINT

Civil Action No. CV 17-6154

WEXLER, J.

TOMLINSON, M.J.

Plaintiff, the UNITED STATES OF AMERICA, by and through its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), hereby alleges as follows:

INTRODUCTION

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, to permanently enjoin and restrain Riddhi USA, Inc. and Mohd M. Alam (collectively, "Defendants"), from violating:

A. 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce dietary supplements, within the meaning of 21 U.S.C. § 321(ff), that are adulterated under 21 U.S.C. § 342(g)(1) and misbranded under 21 U.S.C. §§ 343(e)(1), 343(i)(2), and 343(w)(1)(A); and

B. 21 U.S.C. § 331(k), by causing dietary supplements, within the meaning of 21 U.S.C. § 321(ff), to become adulterated under 21 U.S.C. § 342(g)(1), and misbranded under 21 U.S.C. §§ 343(e)(1), 343(i)(2), and 343(w)(1)(A) while such articles are held for sale after shipment of one or more of their components in interstate commerce.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

PARTIES

4. Defendant Riddhi USA, Inc. ("Riddhi") is a New York corporation with its principal place of business at 2231 5th Avenue, Suites 27 and 28, Ronkonkoma, New York 11779 (the "Facility"), within the jurisdiction of this Court.

5. Defendant Mohd M. Alam is Riddhi's owner and President. Mr. Alam oversees Riddhi's day-to-day operations and is ultimately responsible for all of its activities.

6. Defendants have been, and are now, engaged in manufacturing, preparing, labeling, packing, repacking, holding, and distributing dietary supplements within the meaning of 21 U.S.C. § 321(ff). Defendants are also contract manufacturers of dietary supplements distributed under other companies' names.

7. Defendants deliver finished dietary supplements for introduction into interstate commerce. Defendants also manufacture dietary supplements using components that they receive from outside New York.

DEFENDANTS' VIOLATIONS OF THE ACT

Defendants' Dietary Supplements are Adulterated

8. The Act requires dietary supplement manufacturers to operate in compliance with current good manufacturing practice ("cGMP") for dietary supplements. 21 U.S.C. § 342(g)(1). Manufacturing according to dietary supplement cGMP means that the manufacturing process incorporates a set of controls in the design and production processes to ensure a finished product

of acceptable, predictable, and reliable quality. Dietary supplements not manufactured, prepared, packed, or held in conformance with the cGMP regulations are deemed to be adulterated. 21 U.S.C. § 342(g)(1). The dietary supplement cGMP regulations are set forth at 21 C.F.R. Part 111.

9. FDA most recently inspected Defendants' facility between January 17 and 31, 2017 ("January 2017 inspection"). The January 2017 inspection established that the dietary supplements that Defendants manufacture, prepare, pack, repack, label, hold, and distribute are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they have been prepared, packed, and held under conditions that do not comply with dietary supplement cGMP regulations.

10. During the January 2017 inspection, FDA investigators documented numerous significant deviations from the cGMP regulations, including, but not limited to, the following:

A. Failure to conduct at least one appropriate test to verify the identity of a dietary ingredient, as required by 21 C.F.R. § 111.75(a)(1)(i);

B. Failure to establish product specifications for identity, purity, strength, and composition of their finished dietary supplements, as required by 21 C.F.R. § 111.70(e);

C. Failure to verify that finished dietary supplements meet product specifications for identity, purity, strength, and composition, as required by 21 C.F.R. § 111.75(c);

D. Failure to establish and follow written procedures for quality control operations, as required by 21 C.F.R. § 111.103;

E. Failure to include all required elements of the master manufacturing records ("MMRs"), as required by 21 C.F.R. §§ 111.210;

F. Failure to establish complete batch production records, as required by 21 C.F.R. §§ 111.255(b); and

G. Failure to establish and follow written procedures for the requirements to review and investigate a product complaint, as required by 21 C.F.R. § 111.553.

Defendants' Dietary Supplements are Misbranded

11. During the January 2017 inspection, the FDA investigator collected samples of Defendants' product labeling. Defendants cause their dietary supplements to be misbranded within the meaning of the Act, 21 U.S.C. § 343, in several ways, including, but not limited to, the following:

A. Food (including dietary supplements) is misbranded within the meaning of 21 U.S.C. § 343(e)(1) if its label or labeling fails to declare the place of business of the manufacturer, packer, or distributor. Some of Defendants' dietary supplement labels or labeling, including its labels or labeling for its Prenatal Formula, Osteo Gest, Neuroxygen, Inflam-Ease, and Aller-Ease products, fail to declare the place of business of the manufacturer, packer, or distributor as required by 21 C.F.R. § 101.5;

B. Food (including dietary supplements) is misbranded within the meaning of 21 U.S.C. § 343(i)(2) if its label or labeling fails to declare the common or usual name of each ingredient if the product is fabricated from two or more ingredients. Defendants' products are fabricated from two or more ingredients but fail to declare any ingredients on their product labels or labeling as required by 21 C.F.R. § 101.4; and

C. Food (including dietary supplements) is misbranded within the meaning of 21 U.S.C. § 343(w)(1)(A) if its label or labeling fails to declare the major food allergen "soy," as defined under 21 U.S.C. § 321(qq). Defendants' Neuroxygen dietary supplement product is

manufactured using soy lecithin, which contains "soy," but Defendants fail to list "soy" on the product's label.

12. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce, dietary supplements that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) and misbranded within the meaning of 21 U.S.C. § 343.

13. Defendants violate 21 U.S.C. § 331(k) by causing dietary supplements to become adulterated within the meaning of 21 U.S.C. § 342(g)(1) and misbranded within the meaning of 21 U.S.C. § 343, while such articles are held for sale after shipment of one or more of their components in interstate commerce.

DEFENDANTS' HISTORY OF VIOLATIONS

14. Many of the dietary supplement cGMP deviations observed during FDA's January 2017 inspection are the same as or similar to those observed by FDA during a previous inspection of Defendants' facility that occurred between December 22, 2015, and January 5, 2016, ("January 2016 inspection").

15. FDA has warned Defendants about their ongoing dietary supplement cGMP violations. At the conclusion of the January 2016 inspection (and again after the January 2017 inspection), an FDA investigator issued to Defendant Alam a List of Inspectional Observations ("Form FDA 483") detailing Defendants' numerous violations of the Act and cGMP regulations, and discussed the observed deviations with him. After the January 2016 inspection, Defendant Alam responded to FDA in writing, promising to take corrective actions in response to FDA's observations.

16. Following the January 2016 inspection, FDA issued a Warning Letter dated April 27, 2016, to Defendants, detailing violations of the dietary supplement cGMP regulations observed during that inspection. The dietary supplement cGMP violations noted in the Warning Letter were the same as, or similar to, those observed during FDA's subsequent 2017 inspection. The Warning Letter cautioned that failure to promptly correct the violations, and prevent future ones, could lead to future enforcement action, including an injunction.

17. On May 17, 2016, Defendants responded in writing to the Warning Letter with promises to correct these violations. However, Defendants either did not follow through on their promises to correct violations, as shown by the FDA investigators' observations of the same or similar ongoing, significant cGMP deficiencies during the subsequent 2017 inspection.

18. Based on the foregoing, Plaintiff believes that, unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

COUNT I
(For violations of 21 U.S.C. § 331(a))

19. The United States realleges and incorporates by reference Paragraphs 1 through 18 of this Complaint as though fully set forth herein.

20. By reason of the conduct described herein, Defendants violated, are violating, and are about to violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce dietary supplements, within the meaning of 21 U.S.C. § 321(ff), that are adulterated under 21 U.S.C. § 342(g)(1) and misbranded under 21 U.S.C. §§ 343(e)(1), 343(i)(2), and 343(w)(1)(A).

21. Upon a showing that the Defendants are violating 21 U.S.C. § 331, the United States may obtain a permanent injunction enjoining such violations. 21 U.S.C. § 332(a).

22. As a result of the foregoing, Defendants' conduct should be enjoined pursuant to 21 U.S.C. § 332.

COUNT II
(For violations of 21 U.S.C. § 331(k))

23. The United States realleges and incorporates by reference Paragraphs 1 through 22 of this Complaint as though fully set forth herein.

24. By reason of the conduct described herein, Defendants violated, are violating, and are about to violate 21 U.S.C. § 331(k), by causing dietary supplements, within the meaning of 21 U.S.C. § 321(ff), to become adulterated under 21 U.S.C. § 342(g)(1), and misbranded under 21 U.S.C. §§ 343(e)(1), 343(i)(2), and 343(w)(1)(A) while such articles are held for sale after shipment of one or more of their components in interstate commerce.

25. Upon a showing that the Defendants are violating 21 U.S.C. § 331, the United States may obtain a permanent injunction enjoining such violations. 21 U.S.C. § 332(a).

26. As a result of the foregoing, Defendants' conduct should be enjoined pursuant to 21 U.S.C. § 332.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff United States of America respectfully requests that, pursuant to 21 U.S.C. § 332(a) and the inherent power of the Court, that the Court issue an Order and Final Judgment:

I. ordering Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, to cease manufacturing, preparing, processing, packing, labeling, holding, and distributing dietary supplements at or from the Facility, or at or from any other location(s) at which Defendants manufacture, prepare, process, pack, label, hold,

and/or distribute dietary supplements, now or in the future, unless and until Defendants bring their manufacturing, preparing, processing, packing, labeling, holding, and distributing operations into compliance with the Act and cGMP regulations; and

II. permanently restraining and enjoining Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly:

A. violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce dietary supplements, within the meaning of 21 U.S.C. § 321(ff) that are adulterated under 21 U.S.C. § 342(g)(1) and misbranded under 21 U.S.C. §§ 343(e)(1), 343(i)(2), and 343(w)(1)(A); and

B. violating 21 U.S.C. § 331(k), by causing dietary supplements, within the meaning of 21 U.S.C. § 321(ff), to become adulterated under 21 U.S.C. § 342(g)(1), and misbranded under 21 U.S.C. §§ 343(e)(1), 343(i)(2), and 343(w)(1)(A) while such articles are held for sale after shipment of one or more of their components in interstate commerce; and

III. authorizing the FDA to inspect Defendants' places of business and all records relating to the receipt, manufacturing, preparing, processing, packing, labeling, holding, and distribution of all of Defendants' dietary supplements to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. awarding Plaintiff costs incurred in pursuing this action, including the costs of investigation to date; and

V. for such other and further relief as the Court deems just and proper.

Dated this 23rd day of October, 2017.

Respectfully Submitted,

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